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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,447	12/02/1998	WERNER LUBITZ	P564-8013	3704

7590

05/22/2002

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EXAMINER

MINNIFIELD, NITA M

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/22/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/117,447

Applicant(s)

LUBITZ ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19-24, 26, 28-30, 32-34 and 37-66 is/are pending in the application.
- 4a) Of the above claim(s) 21-24, 26, 28-30, 32-34, 37-45 and 48-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19, 20, 46, 47 and 58-66 is/are rejected.
- 7) ☒ Claim(s) 5-12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 2 sheets
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 20, 23
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The request filed on January 16, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/117447 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicants' amendment filed October 16, 2001 is acknowledged and has been entered. Claims 5-12 have been amended. New claim 66 has been added.

Applicants' amendment filed January 3, 2002 is acknowledged and has been entered. Claims 1, 15 and 66 have been amended. Claims 1-17, 19, 20, 46, 47 and 58-66 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment with the exception of those discussed below.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. This application contains claims 21-24, 26, 28-30, 32-34, 37-45, and 48-57 are drawn to an invention/species nonelected with traverse in Paper No. 8 and 11. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See M.E.P.. § 821.01.

5. Claims 5-12 are objected to because of the following informalities: applicants should insure that all claim language is correct—subject and verb agreement. Appropriate correction is required.

6. Claims 1-3, 13, 14 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyamoto et al (FEMS Microbiology Letters, 1994).

The claims are directed to a nucleic acid sequence, cells, vectors, and a process of producing S-layer proteins.

Miyamoto et al disclose a clone expressing the S-layer protein and that the clone contained the entire coding region of the S-layer protein gene (abstract; p. 13. col. 2). The S-layer protein was expressed in *E. coli* (pp. 13-14). Miyamoto et al disclose that recombinant phages were plated on *E. coli*, amplified with plating on *E. coli*. The S-layer protein gene was subcloned into plasmid vector pUC18 and *E. coli* XL1-Blue was used as a host strain for the plasmid. Subclones expressing the S-layer were detected by an enzyme immunoassay (materials and methods, p. 15). Miyamoto et al also discloses methods of hybridization (materials and methods, p. 15). Although the prior art does not specifically disclose the sequence as set forth in SEQ ID NO: 1, the product, the S-layer protein, appears to be the same and thus the nucleotide/amino acid sequence is inherent. The prior art appears to disclose the claimed invention. Since the Office does not have the facilities for examining and comparing applicants' products and methods with the products and methods of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and method of the prior art (i.e., that the product and method of the prior art does not possess the same material structural

and functional characteristics of the claimed products and methods). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 58 and 61 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7, 8, 10 and 12 of copending Application No. 09/463402. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a process for producing an S-layer protein or

a recombinant S-layer protein comprising a heterologous protein, which can be any protein. The applications use the same nucleic acid sequence that encodes the S-layer protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim⁵1-17, 19, 20, 46, 47 and 58-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 5, 7, 8, 10 and 12 of copending Application No. 09463402 in view of Deblaere et al. The copending application teaches a process for producing an S-layer protein or a recombinant S-layer protein comprising a heterologous protein, which can be any protein. The applications use the same nucleic acid sequence that encodes the S-layer protein as well as the use of *E. coli* as the host cell. The copending does not specifically teach the specific use of the presently claimed heterologous^{proteins} or insertions in to the S-layer protein.

*However, Deblaere et al teach a host cell which is provided with an S-layer comprising a fusion polypeptide consisting essentially of the S-layer protein and a heterologous polypeptide (abstract; p. 6; claims). Deblaere et al teach that the gene for the S-layer protein includes strong promoter sequences, signal peptide coding sequences as well as a transcription termination sequence (p. 2). The prior art teaches recombinant DNA molecules that includes a SLP system capable of expressing and presenting a fusion polypeptide in a wide variety of bacteria (p. 5). Deblaere et al teach that the insertion or heterologous protein can be a physiologically active polypeptide such as an enzyme, a polypeptide drug or a cytokine (interferon), foreign epitope or polypeptide immunogen, etc (p. 9). The

immunogen can be an antigen of a pathogen such as a virus, bacterium, fungus, yeast or parasite (pp. 9-10). Further, the prior art teaches expression vectors and suitable host cells as well as methods of producing the proteins (p. 10-12). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the methods/processes as taught by both the copending application (09/463402) and Deblaere et al with the reasonable expectation of success of obtaining a process to produce pure S-layer protein, a recombinant S-layer protein or a fusion protein comprising the S-layer protein having an insertion of a heterologous polypeptide as presently claimed. The co-pending application sets forth nucleotide sequence of the S-layer protein while both references provide the process methods, cells, and vectors. Deblaere et al provides the motivation and suggestion to insert foreign or heterologous protein (DNA) into the DNA of the S-layer for the purpose of making fusion proteins that are expressed. It is noted that the prior art does not specifically teach the insertion at the specific positions that are set forth in claim 16; however it would have been obvious to a person of ordinary skill in the art at the time the invention was made to insert the foreign DNA at any cleavage site that would still allow for the assembly of the S-layer protein. The claimed invention is prima facie obvious in view of the teachings of co-pending application (09/463402) taken with Deblaere et al, absent any convincing evidence to the contrary.

This is a provisional obviousness-type double patenting rejection.

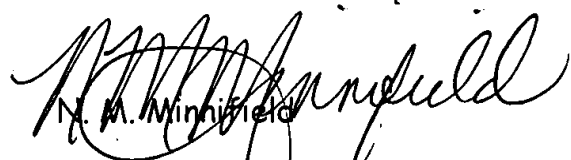
8. No claims are allowed.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


N. M. Minnifield
Primary Examiner
Art Unit 1645
5/10/02

nmm

May 10, 2002